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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/031,752 | 01/23/2002 | Bruce J. Nosky | 46151-268469<br>(18010-0061) | 8340 |

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| EXAMINER | |
|---|---|
| NAVARRO, ALBERT MARK | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/031,752 | NOSKY ET AL | |
| | Examiner | Art Unit | |
| | Mark Navarro | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *11 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *32-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicants response filed December 11, 2003 has been received and entered. Consequently claims 32-53 remain pending in the instant application.

## *SPECIFICATION*

1. Applicants amendment to the first line of the specification is noted. However, Applicants have "claimed benefit" of PCT/US00/20013. The instant application is a 371 filing of PCT/US00/20013. Accordingly the first line of the specification should recite: "This application is a 371 national phase application of PCT/US00/20013, filed July 21, 2000, which claims benefit of U.S. Provisional Application Serial No. 60/145,314, filed July 23, 1999." Appropriate correction is required.

2. Applicants abstract has been received and entered.

## *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. The rejection of claims 32-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,759,554 is maintained.

Applicants have agreed to submit a terminal disclaimer once the claims are considered to be allowable, however, until a terminal disclaimer is made of record this rejection is maintained for reasons of record.

4. The rejection of claims 32-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,632,995 is maintained.

Applicants are asserting that the '995 patent recites claims directed to a method of increasing reproductive performance in a human or animal comprising administering to the human or animal an amount of a nonspecific immunostimulant prepared from a bacterial cell wall extract effective to increase the reproductive performance of the human or animal. The '995 patent defines "reproductive performance" as "an increase in number of offspring, an increase in survival rate of offspring, an increase in first service conception rate and a decrease in service number per conception." (See column 1, lines 19-24). Applicants assert that, in contrast, the present claims are directed to methods for enhancing production performance defined by the specification

as "an increase in the average daily weight gain of an animal, a decrease in the mortality of an animal, a decrease in the number of treatment days necessary to maintain the health of an animal, a decrease in the cost of treatment necessary to maintain the health of an animal, and any combination thereof." (See page 7, lines 12-16).

Applicants conclude that one skilled in the art would not expect that methods for "enhancing production performance" and methods for "increasing reproductive performance" would be interchangeable or even related. Applicants further assert that '995 fails to teach or even suggest that the methods therein would be applicable for enhancing production performance.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be persuasive in view of the disclosure of the '955 patent.

As Applicants have correctly pointed out, the '995 patent, which has claims directed to "methods of increasing reproductive performance," defines reproductive performance as "an increase in number of offspring, ***an increase in survival rate of offspring***, an increase in first service conception rate and a decrease in service number per conception." (See column 1, lines 19-24). (Emphasis added).

Applicants have further argued that the instant claims are directed to "enhancing production performance" which is defined as "an increase in the average daily weight gain of an animal, ***a decrease in the mortality of an animal***, a decrease in the number

of treatment days necessary to maintain the health of an animal, a decrease in the cost of treatment necessary to maintain the health of an animal, and any combination thereof." (See page 7, lines 12-16). (Emphasis added). However, this argument is only partially correct. Applicants will note that claim 32 recites "***wherein the amount is effective to activate the immune system of the animal or*** to enhance production performance of the animal. (Emphasis added). The claims simply do not require that the amount must enhance production performance of the animal as argued by Applicants, only that the amount "activates the immune system."

Finally, Applicants assert that one skilled in the art would not expect that methods for "enhancing production performance" and methods for "increasing reproductive performance" would be interchangeable or even related. However as set forth in bold above, the '995 patent encompasses methods of increasing the survival rate of offspring, whereas the instant filed application encompasses a decrease in the mortality of an animal. Increasing the survival rate of offspring has a direct correlation with a decrease in the mortality rate, accordingly one of skill in the art would find a relation between the terms "enhancing production performance" and "increasing reproductive performance."

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
April 12, 2004